

**ICR-ICP Data System
ABCC Definitions of Terms Used
(Business Metadata)**

QUESTION #	TERM BEING DEFINED	"MOUSE OVER" DEFINITION
1	UNOS ID Number	Indicate the Donor's UNOS ID number.
2	Center-Specific ID Number	Indicate an alternative ID number used in place of or alongside the UNOS ID number
3.1	Intended for	Indicate what the islets were intended to be used for prior to islet isolation.
3.2	Used for	Indicate how the islets were actually used subsequent to islet isolation.
3.2.1	Approval Status	For clinical islets, indicate whether or not the clinical protocol has been approved by the ICR Steering Committee. If 'OTHER' is selected, please clarify approval status in the 'Other' textbox below.
3.2.1.2	Protocol Number	For clinical islets, if the patient is enrolled in an ICR-approved protocol or an ICR protocol pending approval, please indicate the protocol number.
3.2.2	Type of Protocol	For clinical islets, indicate the type of islet transplant procedure that will be performed. If the type of procedure is not listed, select 'OTHER' and list the type of protocol in the textbox below.
3.2.3	ICR Basic Science Use	For basic science islets, indicate whether or not the islets were distributed to an investigator on the ICR Basic Science Distribution Program approved investigator list.
3.2.3.1	Number of approved	For basic science islets, indicate how many ICR Basic Science Distribution Program approved investigators received islets from this isolation.
3.2.4	Non-ICR Basic Science Use Islets	For basic science islets, indicate whether or not any islets from this isolation were given to investigators not on the ICR Basic Science Distribution Program approved investigator list. Do not include investigators who were given islets as part of an ICR related research project.
3.2.5	Own research	For basic science islets, indicate whether or not any islets from this isolation were used for research within your ICR laboratory. This includes both ICR and non-ICR related research.
3.2.5.1	IEQs used research	For basic science islets, indicate the total number of IEQs used from this pancreas to conduct research within your ICR laboratory. This number includes both ICR and non-ICR related research islets.
3.2.6	Pancreas Not Used	If the pancreas was not processed or if the islets were not used for clinical or basic science research studies, please describe why in the textbox below.
4	Date and time of cross clamp	Indicate the date and time the aorta was cross clamped. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). Time zone should be selected from the drop down menu and based on the time zone of the region where the cross clamp took place.
5	Date and time of pancreas recovery	Indicate the date and time the pancreas was recovered from the cadaver in the operating room. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time of pancreas recovery is not known, select the 'UNKNOWN' checkbox to the right.
6.1	Organ intact	Indicate whether or not the pancreas was intact prior to shipment to the ICR. Check 'YES' if the head, body and tail of the pancreas was described as being in one piece, 'NO' if the pancreas was described as being in multiple pieces, or 'UNKNOWN' if the condition of the pancreas prior to shipment was not given.
6.2	Macroscopic damage	Indicate whether or not the pancreas was damaged prior to shipment to the ICR. Check 'YES' if visual damage to the pancreas was noted, 'NO' if it was noted that there was no visual damage to the pancreas, or 'UNKNOWN' if the condition of the pancreas prior to shipment was not given

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6.3	Edema	Indicate whether or not there was swelling in the pancreas prior to shipment to the ICR. Check 'YES' if swelling to the pancreas was noted, 'NO' if it was noted that there was no swelling, or 'UNKNOWN' if the swelling status of the organ prior to shipment was not given.
7.1	Date and time pancreas in preservation for shipping	Indicate the date and time the pancreas was placed in preservation solution for shipping. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time pancreas placed in preservation for shipping is not known, select the 'UNKNOWN' checkbox to the right. If the pancreas was not placed in a preservation solution prior to shipping, select the 'NOT DONE' checkbox to the right.
7.2	Type of preservation solution used for shipping	Select 'UW' if the University of Wisconsin (UW) fluid was the only preservation solution used during shipping of the pancreas. Select 'TWO LAYER' if the two layer method was used to preserve the pancreas during shipping. Select 'EUROCOLLINS' if Eurocollins fluid was the only preservation solution used during the shipping of the pancreas. Select 'HTK' if Histidine-Tryptophan-Ketoglutarate (HTK) fluid was the only preservation solution used during shipping of the pancreas. Select 'CELSIOR' if Celsior was the only preservation solution used during shipping of the pancreas. Select 'OTHER' if the preservation solution used for shipping does not appear in the drop down menu and then type the solution used in the textbox below. If the type of preservation solution used for shipping is not known, select the 'Unknown' checkbox to the right.
7.2.2	Two Layer Method for shipping	Indicate the solution used in both the top and bottom layers of the two layer method.
7.3	Pancreas Preservation after shipping	Select 'NO' if the pancreas was never placed in a different preservation solution once the organ was received by the ICR after shipping. Select 'YES' if the pancreas was placed in a preservation solution different from the one used to preserve the organ during shipping.
7.3.1.1	Date and time pancreas in preservation at ICR (after shipping)	Indicate the date and time the pancreas was placed in a different preservation solution at the ICR laboratory. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). Time zone should be selected from the drop down menu and based on the time zone of the region where the ICR laboratory is located. If the date and/or time pancreas placed in preservation solution at the ICR laboratory is not known, select the 'UNKNOWN' checkbox to the right.
7.3.1.2.1	Type of preservation solution used at the ICR laboratory.	Select 'UW' if the University of Wisconsin (UW) fluid was the only preservation solution used at the ICR laboratory. Select 'TWO LAYER' if the two layer method was used at the ICR laboratory. Select 'EUROCOLLINS' if Eurocollins fluid was the only preservation solution used at the ICR laboratory. Select 'HTK' if Histidine-Tryptophan-Ketoglutarate (HTK) fluid was the only preservation solution used at the ICR laboratory. Select 'CELSIOR' if Celsior was the only preservation solution used at the ICR laboratory. Select 'OTHER' if the preservation solution used at the ICR laboratory does not appear in the drop down menu and then type the solution used in the textbox below. If the type of preservation solution used at the ICR laboratory is not known, select the 'Unknown' checkbox to the right.
7.3.1.2.2	Two Layer Method at the ICR	Indicate the solution used in both the top and bottom layers of the two layer method.
8.1	Duration of preservation during shipping	If the system was not able to automatically calculate the duration of time the pancreas was in shipping preservation solution, manually enter the total time in the hours and minutes numeric boxes to the right. The shipping preservation time begins when the pancreas is first placed in the preservation solution at the organ procurement site and ends when either pancreas dissection at the ICR laboratory begins or the ICR laboratory places the pancreas in a different preservation solution after shipping was completed. Total time should be expressed in cumulative hours and minutes. For example, if duration of time pancreas in shipping preservation solution was 50 minutes, enter '0' for hours and '50' for minutes; if it was 3 hours and 10 minutes, enter '3' for hours and '10' for minutes.

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8.2	Duration of preservation in ICR solution after shipping	If the pancreas was placed in a different preservation solution by the ICR laboratory after shipping and the system was not able to automatically calculate the duration of time the pancreas was in ICR preservation solution, manually enter the total time in the hours and minutes numeric boxes to the right. The ICR preservation time begins when the pancreas is first removed from the shipping solution and placed into the ICR preservation solution and ends when pancreas dissection at the ICR laboratory begins. Total time should be expressed in cumulative hours and minutes. For example, if duration of time pancreas in shipping preservation solution was 50 minutes, enter '\0\' for hours and '\50\' for minutes; if it was 3 hours and 10 minutes, enter '\3\' for hours and '\10\' for minutes.
8.3	Total duration of preservation	If the system was not able to automatically calculate the total duration of preservation, manually enter the total time in the hours and minutes numeric boxes to the right. The total duration of preservation starts with the pancreas is first placed in preservation solution at the organ procurement site and ends when pancreas dissection at the ICR laboratory begins. Total time should be expressed in cumulative hours and minutes. For example, if total duration of preservation was 50 minutes, enter '\0\' for hours and '\50\' for minutes; if it was 3 hours and 10 minutes, enter '\3\' for hours and '\10\' for minutes.
9	Duration of cold ischemia	Indicate the cumulative time in hours and minutes of cold ischemia. For example, if the duration was 50 minutes, enter '\0\' for hours and '\50\' for minutes, or if it was 3 hours and 10 minutes, enter '\3\' for hours and '\10\' for minutes. If cold ischemia cannot be calculated, select the '\UNKNOWN\' checkbox to the right.
10	Definition of cold ischemia	Indicate how the cold ischemia time was defined. Specify if the calculation was based on '\TIME FROM AORTIC CROSS CLAMP TO START OF TRIMMING\'', '\TIME FROM AORTIC CROSS CLAMP TO INITIAL COLLAGENASE INJECTION\'', '\TIME FROM END OF PANCREATECTOMY TO INITIAL COLLAGENASE INJECTION\'', '\TIME FROM AORTIC CROSS CLAMP TO THE START OF DIGESTION (PHASE I)\' or '\OTHER\''. If '\OTHER\' is selected, describe how the cold ischemia time was defined in the textbox below.
11	Pancreas procurement team	Indicate if the pancreas procurement team was '\RELATED TO THE ICR PROCESSING/TRANSPLANT TEAM\'', or '\UNRELATED TO THE ICR PROCESSING/TRANSPLANT TEAM\''. If this information is not known, select '\UNKNOWN\''. The term related describes a procurement team that resides at the same institution/hospital and in the same city as the processing/transplant team. For example, if the procurement team is affiliated with the Kaiser Health System in Los Angeles and the transplant team is at the University of Texas, they are unrelated. If the transplant team is affiliated with the Kaiser Health System in Georgia, they are also unrelated. If one or more members of the processing/transplant team helps or performs with the procurement team, this would be defined as related, regardless of the city in which the procurement occurs.
12.1	Organ intact	Indicate whether or not the pancreas was intact upon arrival at the ICR. Check '\YES\' if the head, body and tail of the pancreas was in one piece, '\NO\' if the pancreas was in multiple pieces, or '\UNKNOWN\' if the condition of the pancreas upon arrival at the ICR not known.
12.2	Macroscopic damage	Indicate whether or not the pancreas was damaged upon arrival at the ICR. Check '\YES\' if there was visual damage to the pancreas, '\NO\' if there was no visual damage to the pancreas, or '\UNKNOWN\' if the condition of the pancreas upon arrival at the ICR was not known.
12.3	Edema	Indicate whether or not there was swelling in the pancreas upon arrival at the ICR. Check '\YES\' if the pancreas was swollen, '\NO\' if pancreas was not swollen, or '\UNKNOWN\' if the swelling status of the pancreas upon arrival at the ICR was not known.
13	Surface fat	Indicate how fatty the surface of the pancreas was upon arrival at the ICR. Select if the surface fat was '\CLEAN\'', '\LIGHT\'', '\MODERATE\'', or '\HEAVY\'.

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14	Fat Infiltration	Indicate how infiltrated the interior of the pancreas was with fat upon arrival at the ICR. Select if the fat infiltration was 'NONE', 'PATCHY', 'MODERATE', or 'HEAVY'
15	Free Text Comments - Pancreas Characterization at ICR	If additional information needs to be considered about the characterization of the pancreas at the ICR, please indicate the information in the textbox.
16	Collagenase lots and concentrations	Various lots and concentrations of collagenase may be used during pancreas perfusion. In addition, each manufacturer can make several types of collagenase. The following questions should be filled in for EACH lot of collagenase used during the perfusion of this pancreas.
16.1	Collagenase Manufacturer	For each lot of collagenase, indicate the company who manufactured the collagenase. If the manufacturer is not listed, select 'OTHER' and indicate the manufacturer in the textbox below. If the manufacturer is not known, select 'UNKNOWN'.
16.2	Collagenase Type	For each lot of collagenase, indicate the type of collagenase used. If the type of collagenase is not listed, select 'OTHER' and indicate the type in the textbox below. If the type is not known, select 'UNKNOWN'.
16.3	Base Medium	Select the primary solution used to dilute the specified collagenase. If the base medium is not listed, select 'Other' and indicate the base medium in the textbox below.
16.4	Additives	If additives were not added to the collagenase solution, select 'NO'. If additives were added to the collagenase solution, select 'YES'. If it is not known if additives were added to the collagenase solution, select 'UNKNOWN'.
16.4.1	Select all additives	If additives were used with the collagenase solution, select all the additives from the list below. If the additives used do not appear in the pre-determined list, use the textbox to submit as many additives as needed.
16.5	Collagenase Lot Number	Indicate the lot number of the collagenase.
16.6	Final collagenase concentration	Indicate the collagenase concentration of the final solution used for pancreas perfusion and select the units of concentration from the pre-defined list.
16.7	Final neutral protease concentration	If the neutral protease was prepared separately from the collagenase (e.g. Serva NB1), indicate the neutral protease concentration of the final solution used for pancreas perfusion and select the units of concentration from the pre-defined list.
16.8	Final volume	Indicate the total volume of pancreas perfusion solution prepared. The volume should be expressed in mL.
17	Dissection start date and time	Indicate the date and time pancreas dissection began. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time dissection in lab started is not known, select the 'UNKNOWN' checkbox to the right.
18	Pancreas Temperature pre-dissection	Indicate the temperature of the pancreas before dissection began. Temperature should be expressed in degrees Celsius. If the measurement was not taken, select the 'MEASUREMENT NOT TAKEN' checkbox to the right.
19	Dissection end date and time	Indicate the date and time pancreas dissection ended. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time dissection in lab completed is not known, select the 'UNKNOWN' checkbox to the right.
20	Pancreas Temperature post-dissection	Indicate the temperature of the pancreas after dissection was completed. Temperature should be expressed in degrees Celsius. If the measurement was not taken, select the 'MEASUREMENT NOT TAKEN' checkbox to the right.
21	Duration of dissection	If the system was not able to automatically calculate the total duration of dissection, manually enter the total time in the hours and minutes numeric boxes to the right. The total duration of dissection starts when the dissection of the pancreas begins and ends when dissection is completed. Total time should be expressed in cumulative hours and minutes. For example, if total duration of preservation was 50 minutes, enter '0' for hours and '50' for minutes; if it was 3 hours and 10 minutes, enter '3' for hours and '10' for minutes.

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22	Pre-distention weight	Indicate the weight of the pancreas prior to distention. Weight should be expressed in grams.
23.1	Distention type body and tail	Indicate the type of distention used on the body and tail of the pancreas. If distention was performed by hand, select 'MANUAL'. If it was automated, select 'MECHANICAL'. If distention was not performed, select 'NOT DONE'.
23.2	Distention type head	Indicate the type of distention used on the head of the pancreas. If distention was performed by hand, select 'MANUAL'. If it was automated, select 'MECHANICAL'. If distention was not performed, select 'NOT DONE'.
24	Date and Time of Initial Collagenase Injection	Indicate the date and time of initial collagenase injection into the pancreas (i.e. start of perfusion). Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). Time zone should be selected from the drop down menu and based on the time zone of the region where the ICR laboratory is located. If the date and/or time of initial collagenase injection is not known, select the 'UNKNOWN' checkbox to the right.
25	Perfusion Measurements	If multiple measurements of temperature, pressure, and/or flow rate were collected during any part of the perfusion process, select 'YES'. If there were no measurements taken during perfusion, then select 'NO'.
25.1	Perfusion data	Indicate the temperature, pressure, and or flow rate used for the perfusion of the Body and Tail and/or Head section(s) of the pancreas at each time point. Click on the 'ADD PERFUSION' button to add as many rows as needed to enter all the time points for your perfusion data. Temperature should be expressed in degrees Celsius. Pressure should be expressed in millimeter Mercury. Flow rate should be expressed in milliliters per minute.
26	Distention quality	Indicate your subjective opinion of the quality of the pancreas distention.
27	Date and time perfusion ended	Indicate the date and time perfusion ended. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time perfusion ended is not known, select the 'UNKNOWN' checkbox to the right.
28	Perfusion duration	If the system was not able to automatically calculate the duration perfusion, manually enter the total time in the hours and minutes numeric boxes to the right. The duration of perfusion begins when the pancreas is first injected with collagenase and ends when perfusion is completed. Total time should be expressed in cumulative hours and minutes. For example, if duration of perfusion was 50 minutes, enter '0' for hours and '50' for minutes; if it was 3 hours and 10 minutes, enter '3' for hours and '10' for minutes.
29	Digestion method	Indicate the method used to digest the pancreas. If a standard Ricordi method was used, select 'RICORDI METHOD'. If a modification of the original procedure was made, such as a different chamber size, chamber composition or other modification, select 'MODIFIED RICORDI'. If the Ricordi method was not used at all, select 'OTHER' and describe the method in the textbox below.
30	Start of digestion phase	Indicate the date and time digestion phase (Phase I) started. This phase begins when the collagenase is first circulated through the chamber. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time digestion phase started is not known, select the 'UNKNOWN' checkbox to the right.
31	End of digestion phase	Indicate the date and time digestion phase (Phase I) stopped. This phase ends when the dilution phase (Phase II) begins. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time digestion phase stopped is not known, select the 'UNKNOWN' checkbox to the right.
32	Duration of Digestion	If the system was not able to automatically calculate the total time of Phase I digestion, manually enter the total time in the hours and minutes numeric boxes to the right. This phase begins when the collagenase is circulated through the chamber and ends when dilution begins. Total time should be expressed in cumulative hours and minutes. For example, if Phase I digestion was 50 minutes, enter '0' for hours and '50' for minutes; if it was 3 hours and 10 minutes, enter '3' for hours and '10' for minutes.

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33	Criteria for start of dilution	Indicate the criteria used to switch from the digestion (Re-circulation Phase I) to the dilution (Phase II) phase. Check '% OF FREE ISLETS OBSERVED', '% OF EMBEDDED ISLETS OBSERVED', 'SIZE OF ISLETS', and/or 'OTHER'. Select 'OTHER' if the reason for switching phases is not listed and then type the criteria used in the textbox below.
34	Start of dilution phase	Indicate the date and time dilution phase (Phase II) started. This phase begins when fresh solution (without collagenase) is circulated through the chamber. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time dilution phase started is not known, select the 'UNKNOWN' checkbox to the right.
35	End of dilution phase	Indicate the date and time dilution phase (Phase II) stopped. This phase ends when the dilution is completed. Date is selected from the drop down calendar and will be in the month/day/full year format. Time should be entered in military format (hh:mm). If the date and/or time dilution phase stopped is not known, select the 'UNKNOWN' checkbox to the right.
36	Duration of dilution phase	If the system was not able to automatically calculate the total time of Phase II dilution, manually enter the total time in the hours and minutes numeric boxes to the right. This phase begins when digestion is completed and ends when dilution is completed. Total time should be expressed in cumulative hours and minutes. For example, if Phase II dilution was 50 minutes, enter '0' for hours and '50' for minutes; if it was 3 hours and 10 minutes, enter '3' for hours and '10' for minutes.
37	Type of dilution solution used	Select the primary solution used during the dilution phase (Phase II). If the solution is not listed, select 'Other' and indicate the solution in the textbox below.
37.2	Dilution solution additives	If additives were not added to the dilution solution, select 'NO'. If additives were added to the dilution solution, select 'YES'.
37.2.1	Select all dilution solution additives	If additives were used with the dilution solution, select all the additives from the list below. If the additives used do not appear in the pre-determined list, use the textbox to submit as many additives as needed.
38	Quality of digestion	Indicate your subjective opinion of the quality of the pancreas digestion.
39	Comments on digestion	If additional information needs to be considered about the digestion process and/or the quality of digestion, please indicate the information in the textbox.
40	Islet count pre-purification	If an islet count was not taken before purification began, select 'NO'. If an islet count was taken after digestion and before purification began, select 'YES'.
40.1	Total IEQs	Indicate the total number of islet equivalents (IEQs) in the post digestion sample.
41	Other Islet Characterization Parameters	If no other islet characterization parameters were measured before purification, select 'NO'. If there were other islet characterization parameters measured after digestion and before purification, select 'YES'.
41.1.1	Total digestate volume	Indicate the total volume of digestate used for purification and/or counting. This would be the total volume of fluid collected during the digestion process. The volume should be expressed in mL. If the total volume of digestate is not known, select the 'UNKNOWN' checkbox to the right. If the total volume of digestate was a number that was not collected, select the 'NOT DONE' checkbox to the right.
41.1.2	Total packed cell volume	Indicate the total packed cell volume of the post digestion sample. The volume should be expressed in mL. If the total packed cell volume is not known, select the 'UNKNOWN' checkbox to the right. If the total packed cell volume was not calculated, select the 'NOT DONE' checkbox to the right.
41.1.3	Percent trapped islets	Indicate the percentage of trapped islets in relation to the total isolated islets in the post digestion sample. Trapped islets may also be labeled as embedded or mantled islets. Percentage is expressed as a % not as hundredths. For example, if a third of the islets were trapped, enter '33.3' not 0.333. If the percentage of trapped islets is not known, select the 'UNKNOWN' checkbox to the right. If the percentage of trapped islets was not calculated, select the 'NOT DONE' checkbox to the right.
41.1.4	Gross clumping evident	Indicate whether or not there was evidence of gross clumping in the post digestion sample. If gross clumping was present, select 'YES'. If no clumping was present, select 'NO'. If this information is not known, select the 'UNKNOWN' checkbox to the right. If gross clumping was not assessed, select the 'NOT DONE' checkbox to the right.

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41.1.5	Insulin Content	Indicate the insulin content in the post digestion sample. Insulin content should be expressed in $\mu\text{U}/\text{IEQ}$. If the insulin content is not known, select the 'UNKNOWN' checkbox to the right. If the insulin content was not calculated, select the 'NOT DONE' checkbox to the right.
41.1.6	DNA Content	Indicate the DNA content in the post digestion sample. DNA content should be expressed in ng/IEQ . If the DNA content is not known, select the 'UNKNOWN' checkbox to the right. If the DNA content was not calculated, select the 'NOT DONE' checkbox to the right.
41.1.7.1	Stimulation Index	Indicate the stimulation index for the post digestion sample. To obtain the stimulation index take the glucose-stimulated insulin release at high glucose divided by the glucose-stimulated insulin release at low glucose. If one or both pieces of this information is not known, select the 'UNKNOWN' checkbox to the right. If the stimulation index was not assessed, select the 'NOT DONE' checkbox to the right.
41.1.8.1	% dithizone positive	Indicate the percentage of cells that were dithizone positive in relation to all cells assessed in the post digestion sample. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were dithizone positive, enter '33' not 0.333. If the percentage of dithizone positive cells is not known, select the 'UNKNOWN' checkbox to the right. If dithizone staining was not conducted, select the 'NOT DONE' checkbox to the right.
41.1.9.1	Inclusion Dye	Indicate the type of inclusion dye used to determine Islet Viability. Select 'ACRIDINE ORANGE', 'FLUORESCEIN DIACETATE', or 'OTHER' if the inclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the inclusion dye in the textbox below. If the type of inclusion dye is not known, select 'UNKNOWN'. If islet viability was not determined at this stage, select 'NOT DONE'.
41.1.9.2	Exclusion Dye	Indicate the type of exclusion dye used to determine Islet Viability. Select 'ETHIDIUM BROMIDE', 'PROPIDIUM IODIDE', 'TRYPAN BLUE', or 'OTHER' if the exclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the exclusion dye in the textbox below. If the type of exclusion dye is not known, select 'UNKNOWN'. If islet viability was not determined at this stage, select 'NOT DONE'.
41.1.9.3	Islet Viability	Indicate the islet viability of the islets assessed in the post digestion sample. Islet viability should be expressed as a percentage. Percentage is expressed as a % not as hundredths. For example, if the islet viability was 33%, enter '33' not 0.333.
42	Islet Purification	Indicate the type of islet purification used. Select 'DENSITY GRADIENT' if a density gradient was used to purify the islets post digestion, regardless of method (e.g. COBE, flask, etc.). Select 'OTHER' if a different method was used. If 'Other' is selected, describe the method in the textbox below. If islet purification was not performed, select 'NOT DONE'.
43	COBE	Indicate whether or not a COBE was used to purify the islets. Select 'NO' if a COBE was not used or select 'YES' if a COBE was used to purify the islets.
44	Type of gradient used	Indicate the type of gradient used. Select 'DISCONTINUOUS' if the gradients were separated by layers. Select 'CONTINUOUS' if gradient changes were gradual and not separated by layers.
45	Describe gradient	Indicate whether the gradient was 'BIOCOLL', 'EURO-FICOLL', 'FICOLL', 'OPTIPREP', or 'OTHER'. If 'OTHER' is selected describe the gradient in the textbox below.
46	Total packed cell volume	Indicate the total packed cell volume of the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the total packed cell volume for each fraction separately. The volume should be expressed in mL. If the total packed cell volume is not known, select the 'UNKNOWN' checkbox to the right. If the total packed cell volume was not calculated, select the 'NOT DONE' checkbox to the right.

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48	Total Islet Count	Indicate the total islet count (not the total IEQ count) in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the total islet count for each fraction separately.
49	Gross clumping evident	Indicate whether or not there was evidence of gross clumping in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate whether or not gross clumping was evident for each fraction separately. If gross clumping was present, select '\YES\ '. If no clumping was present, select '\NO\ '. If this information is not known, select the '\UNKNOWN\ ' checkbox to the right. If gross clumping was not assessed, select the '\NOT DONE\ ' checkbox to the right.
50	Total IEQs	Indicate the total number of islet equivalents (IEQs) in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the total number of IEQs for each fraction separately.
51	Total # of beta cells	Indicate the total number of beta cells in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the total number of beta cells for each fraction separately. This number will be x 10 ⁶ . If the total number of beta cells is not known, select the '\UNKNOWN\ ' checkbox to the right. If the beta cells were not counted, select the '\NOT DONE\ ' checkbox to the right.
52	Insulin Content	Indicate the insulin content in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the insulin content for each fraction separately. Insulin content should be expressed in $\mu\text{U}/\text{IEQ}$. If the insulin content is not known, select the '\UNKNOWN\ ' checkbox to the right. If the insulin content was not calculated, select the '\NOT DONE\ ' checkbox to the right.
53	DNA Content	Indicate the DNA content in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the DNA content for each fraction separately. DNA content should be expressed in ng/IEQ. If the DNA content is not known, select the '\UNKNOWN\ ' checkbox to the right. If the DNA content was not calculated, select the '\NOT DONE\ ' checkbox to the right.
54.1	Stimulation Index	Indicate the stimulation index for the post purification sample. To obtain the stimulation index take the glucose-stimulated insulin release at high glucose divided by the glucose-stimulated insulin release at low glucose. If one or both pieces of this information is not known, select the '\UNKNOWN\ ' checkbox to the right. If the stimulation index was not assessed, select the '\NOT DONE\ ' checkbox to the right.
55.1	% dithizone positive	Indicate the percentage of cells that were dithizone positive in relation to all cells assessed in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the islet purity for each fraction separately. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were dithizone positive, enter '\33\ ' not 0.333. If the percentage of dithizone positive cells is not known, select the '\UNKNOWN\ ' checkbox to the right. If dithizone staining was not conducted, select the '\NOT DONE\ ' checkbox to the right.

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55.2	% beta cells	Indicate the percentage of beta cells in relation to all cells assessed in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the % beta cells for each fraction separately. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were beta cells, enter '\33.3%' not 0.333. If the percentage of beta cells is not known, select the '\UNKNOWN' checkbox to the right. If the beta cell percentage was not assessed, select the '\NOT DONE' checkbox to the right.
56.1	Inclusion Dye	Indicate the type of inclusion dye used to determine Islet Viability if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the inclusion dye used for each fraction separately (may be the same for each fraction). Select '\ACRIDINE ORANGE', '\FLOURESCIEIN DIACETATE', or '\OTHER' if the inclusion dye you used does not appear on the list. If '\OTHER' is selected, type the name of the inclusion dye in the textbox below. If the type of inclusion dye is known, select '\UNKNOWN'. If islet viability was not determined at this stage, select '\NOT DONE'.
56.2	Exclusion Dye	Indicate the type of exclusion dye used to determine Islet Viability if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the exclusion dye used for each fraction separately (may be the same for each fraction). Select '\ETHIDIUM BROMIDE', '\PROPIDIUM IODIDE', '\TRYPAN BLUE', or '\OTHER' if the exclusion dye you used does not appear on the list. If '\OTHER' is selected, type the name of the exclusion dye in the textbox below. If the type of exclusion dye is not known, select '\UNKNOWN'. If islet viability was not determined at this stage, select '\NOT DONE'.
56.3	Islet Viability	Indicate the islet viability of the islets assessed in the post purification sample if only one purification fraction exists. If multiple purification fractions are collected and kept separate, indicate the islet viability for each fraction separately. Islet viability should be expressed as a percentage. Percentage is expressed as a % not as hundredths. For example, if the islet viability was 33%, enter '\33%' not 0.333.
57	Temperature during purification	Indicate the temperature during the purification process. Temperature should be expressed in degrees Celsius. If the measurement was not taken, select the '\MEASUREMENT NOT TAKEN' checkbox to the right.
57.1	Temperature determination	If the temperature was recorded during purification, indicate how the temperature was determined. Select '\ROOM READING TEMPERATURE' if the temperature was determined based on room temperature readings during purification. Select '\REFRIGERATED COBE READING' if the temperature was based on a refrigerated COBE reading taken from the COBE. Select '\COLD ROOM READING' if the purification was done in a cold room and the temperature was based on the cold room temperature. Select '\OTHER' if the purification temperature was determined using a method not listed, and describe how the temperature was measured in the textbox below.
58	Supplemental Islet Processing	Indicate if the islets underwent supplemental processing following purification. If the islets never underwent a supplemental processing treatment, select the '\NOT DONE' checkbox to the right. If the islets did undergo supplemental processing, select the checkboxes to the left of ALL processes that apply from the choices below. If the islets went through a supplemental process not listed, select '\OTHER' and describe the type of supplemental treatment in the textbox below.
58.1	Culture	If the islets were cultured prior to end use (transplantation or basic research), select the checkbox to the right. Complete additional questions related to culture of the islets.
58.2	Cryopreservation	If islets were cryopreserved prior to end use (transplantation or basic research), select the checkbox to the right.
58.3	Irradiation	If islets were irradiated prior to end use (transplantation or basic research), select the checkbox to the right.
58.4	Gene Transfer	If islets went through gene transfer prior to end use (transplantation or basic research), select the checkbox to the right.
58.5	Other	If the islets went through a pretreatment process not listed, select the checkbox to the right and describe the type of islet pretreatment in the textbox below.
58.1.1	Culture Formulation	Indicate the culture formulation below. The formulation is defined by the base medium and additives used.
58.1.1.1	Base Medium	Indicate the base medium used for culture. The base medium is the main solvent used in the culture formulation. If the base medium does not appear on the list, select '\OTHER' and enter the base medium used in the textbox below. If the base medium is proprietary, select '\OTHER' and type 'proprietary' in the textbox below.

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58.1.1.2	Additives	If additives were not added to the base medium, select 'NO'. If additives were added to the base medium, select 'YES'.
58.1.1.2.1	Additives List	If additives were used with the base medium, select all the additives used from the list below. If the additives used do not appear in the pre-determined list, use the textbox to submit as many additives as needed. If any proprietary additives were used in addition to or in lieu of any additives on the list, select 'PROPRIETARY' from the list.
58.1.2	Surface Area	Indicate the surface area of the flasks used to culture the islets. Surface area should be expressed in units of cm ²
58.1.3	Total Volume	Indicate the total volume of islets (including the culture medium) that was placed into each culture flask. Total volume should be expressed in units of mL.
58.1.4	Islet Density	Indicate the islet density of the islets being cultured. Density should be expressed in units of IEQ/mL.
58.1.5	Temperature during culture	Indicate the temperature during the duration of culture. If multiple temperature readings were taken during culture, enter the duration of culture at each temperature. For example, if the islets were cultured at 25 degrees Celsius for 10 hours and then at 30 degrees Celsius for 2 days and 5 hours, culture period 1 would be defined as 25 degrees Celsius, 0 days, and 10 hours. To add culture period 2, one must click on the 'ADD CULTURE PERIOD' button and then enter 30 degrees Celsius, 2 days, and 5 hours. Use the 'ADD CULTURE PERIOD' button to add as many culture periods as needed.
58.1.6	Total Culture time	If the system was not able to automatically calculate the total culture time, manually enter the total time the islets were cultured in the days and hours numeric boxes to the right.
58.1.7	Formulation change	If the culture formulation remained the same throughout culture, select 'NO'. If the culture formulation changed anytime during culture, select 'YES'.
58.1.7.1	Formulation change specifics	Indicate what part(s) of the culture formulation changed during culture. Select 'BASE MEDIUM' if the base medium was the only component of the culture formulation that changed during culture. Select 'ADDITIVES USED' if the additives used were the only changes made to the culture formulation during culture. Select 'BOTH' if both the base medium and the additives used changed during culture.
59	Total packed cell volume	Indicate the total packed cell volume of the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the total packed cell volume for each batch separately. The volume should be expressed in mL. If the total packed cell volume is not known, select the 'UNKNOWN' checkbox to the right. If the total packed cell volume was not calculated, select the 'NOT DONE' checkbox to the right.
60	Percent trapped islets	Indicate the percentage of trapped islets in relation to the total isolated islets in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the percentage of trapped islets for each batch separately. Trapped islets may also be labeled as embedded or mantled islets. Percentage is expressed as a % not as hundredths. For example, if a third of the islets were trapped, enter '33.3' not 0.333. If the percentage of trapped islets is not known, select the 'UNKNOWN' checkbox to the right. If the percentage of trapped islets was not calculated, select the 'NOT DONE' checkbox to the right.
61	Total Islet Count	Indicate the total islet count (not the total IEQ count) in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the total islet count for each batch separately.
62	Gross clumping evident	Indicate whether or not there was evidence of gross clumping in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate whether or not gross clumping was evident for each batch separately. If gross clumping was present, select 'YES'. If no clumping was present, select 'NO'. If this information is not known, select the 'UNKNOWN' checkbox to the right. If gross clumping was not assessed, select the 'NOT DONE' checkbox to the right.
63	Total IEQs	Indicate the total number of islet equivalents (IEQs) in the post supplemental processing sample if only one batch fraction exists. If multiple batches are collected and kept separate, indicate the total number of IEQs for each batch separately.

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64	Total # of beta cells	Indicate the total number of beta cells in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the total number of beta cells for each batch separately. This number will be x 10 ⁶ . If the total number of beta cells is not known, select the 'UNKNOWN' checkbox to the right. If the beta cells were not counted, select the 'NOT DONE' checkbox to the right.
65	Insulin Content	Indicate the insulin content in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the insulin content for each batch separately. Insulin content should be expressed in μU/IEQ. If the insulin content is not known, select the 'UNKNOWN' checkbox to the right. If the insulin content was not calculated, select the 'NOT DONE' checkbox to the right.
66	DNA Content	Indicate the DNA content in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the DNA content for each batch separately. DNA content should be expressed in ng/IEQ. If the DNA content is not known, select the 'UNKNOWN' checkbox to the right. If the DNA content was not calculated, select the 'NOT DONE' checkbox to the right.
67.1	Stimulation Index	Indicate the stimulation index for the post supplemental processing sample. To obtain the stimulation index take the glucose-stimulated insulin release at high glucose divided by the glucose-stimulated insulin release at low glucose. If one or both pieces of this information is not known, select the 'UNKNOWN' checkbox to the right. If the stimulation index was not assessed, select the 'NOT DONE' checkbox to the right.
68.1	% dithizone positive	Indicate the percentage of cells that were dithizone positive in relation to all cells assessed in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the islet purity for each batch separately. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were dithizone positive, enter '33' not 0.33. If the percentage of dithizone positive cells is not known, select the 'UNKNOWN' checkbox to the right. If dithizone staining was not conducted, select the 'NOT DONE' checkbox to the right.
68.2	% beta cells	Indicate the percentage of beta cells in relation to all cells assessed in the post supplemental processing sample if only one batch exists. If multiple batches are collected and kept separate, indicate the % beta cells for each batch separately. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were beta cells, enter '33.3' not 0.333. If the percentage of beta cells is not known, select the 'UNKNOWN' checkbox to the right. If the beta cell percentage was not assessed, select the 'NOT DONE' checkbox to the right.
69.1	Inclusion Dye	Indicate the type of inclusion dye used to determine Islet Viability if only one batch exists. If multiple batches are collected and kept separate, indicate the inclusion dye used for each batch separately (may be the same for each batch). Select 'ACRIDINE ORANGE', 'FLOURESCHEIN DIACETATE', or 'OTHER' if the inclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the inclusion dye in the textbox below. If the type of inclusion dye is not known, select 'UNKNOWN'. If islet viability was not determined at this stage, select 'NOT DONE'.
69.2	Exclusion Dye	Indicate the type of exclusion dye used to determine Islet Viability if only one batch exists. If multiple batches are collected and kept separate, indicate the exclusion dye used for each batch separately (may be the same for each fraction). Select 'ETHIDIUM BROMIDE', 'PROPIDIUM IODIDE', 'TRYPAN BLUE', or 'OTHER' if the exclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the exclusion dye in the textbox below. If the type of exclusion dye is not known, select 'UNKNOWN'. If islet viability was not determined at this stage, select 'NOT DONE'.

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69.3	Islet Viability	Indicate the islet viability of the islets assessed in the post supplemental processing if only one batch exists. If multiple batches are collected and kept separate, indicate the islet viability for each batch separately. Islet viability should be expressed as a percentage. Percentage is expressed as a % not as hundredths. For example, if the islet viability was 33%, enter '33' not 0.333.
70	Final Characterization	If final islet characterization measurements taken immediately before transplant (or before final release for research) that are representative of the entire islet production batch, select 'YES'. If final islet characterization measurements are not representative of the entire islet production batch, select 'NO'.
70.1.1	Total packed cell volume	Indicate the total packed cell volume of the final islet preparation. The volume should be expressed in mL. If the total packed cell volume is not known, select the 'UNKNOWN' checkbox to the right. If the total packed cell volume was not calculated, select the 'NOT DONE' checkbox to the right.
70.1.2	Percent trapped islets	Indicate the percentage of trapped islets in relation to the total isolated islets in the final islet preparation. Trapped islets may also be labeled as embedded or mantled islets. Percentage is expressed as a % not as hundredths. For example, if a third of the islets were trapped, enter '33.3' not 0.333. If the percentage of trapped islets is not known, select the 'UNKNOWN' checkbox to the right. If the percentage of trapped islets was not calculated, select the 'NOT DONE' checkbox to the right.
70.1.3	Total Islet Count	Indicate the total islet count (not the total IEQ count) of the final islet preparation.
70.1.4	Gross clumping evident	Indicate whether or not there was evidence of gross clumping in the final islet preparation. If gross clumping was present, select 'YES'. If no clumping was present, select 'NO'. If this information is not known, select the 'UNKNOWN' checkbox to the right. If gross clumping was not assessed, select the 'NOT DONE' checkbox to the right.
70.1.5	Total IEQs	Indicate the total number of islet equivalents (IEQs) in the final islet preparation.
70.1.6	Total # of beta cells	Indicate the total number of beta cells in the final islet preparation. This number will be $\times 10^6$. If the total number of beta cells is not known, select the 'UNKNOWN' checkbox to the right. If the beta cells were not counted, select the 'NOT DONE' checkbox to the right.
70.1.7	Insulin Content	Indicate the insulin content in the final islet preparation. Insulin content should be expressed in $\mu\text{U}/\text{IEQ}$. If the insulin content is not known, select the 'UNKNOWN' checkbox to the right. If the insulin content was not calculated, select the 'NOT DONE' checkbox to the right.
70.1.8	DNA Content	Indicate the DNA content in the final islet preparation. DNA content should be expressed in ng/IEQ . If the DNA content is not known, select the 'UNKNOWN' checkbox to the right. If the DNA content was not calculated, select the 'NOT DONE' checkbox to the right.
70.1.9.1	Stimulation Index	Indicate the stimulation index for the final islet preparation. To obtain the stimulation index take the glucose-stimulated insulin release at high glucose divided by the glucose-stimulated insulin release at low glucose. If one or both pieces of this information is not known, select the 'UNKNOWN' checkbox to the right. If the stimulation index was not assessed, select the 'NOT DONE' checkbox to the right.
70.1.10.1	% dithizone positive	Indicate the percentage of cells that were dithizone positive in relation to all cells assessed in the final islet preparation. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were dithizone positive, enter '33' not 0.333. If the percentage of dithizone positive cells is not known, select the 'UNKNOWN' checkbox to the right. If dithizone staining was not conducted, select the 'NOT DONE' checkbox to the right.
70.1.10.2	% beta cells	Indicate the percentage of beta cells in relation to all cells assessed in the final islet preparation. Percentage is expressed as a % not as hundredths. For example, if a third of the cells were beta cells, enter '33.3' not 0.333. If the percentage of beta cells is not known, select the 'UNKNOWN' checkbox to the right. If the beta cell percentage was not assessed, select the 'NOT DONE' checkbox to the right.
70.1.11.1	Inclusion Dye	Indicate the type of inclusion dye used to determine Islet Viability of the final islet preparation. Select 'ACRIDINE ORANGE', 'FLOURESCCEIN DIACETATE', or 'OTHER' if the inclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the inclusion dye in the textbox below. If the type of inclusion dye is not known, select 'UNKNOWN'. If islet viability was not determined at this stage, select 'NOT DONE'.

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70.1.11.2	Exclusion Dye	Indicate the type of exclusion dye used to determine Islet Viability of the final islet preparation. Select 'ETHIDIUM BROMIDE', 'PROPIDIUM IODIDE', 'TRYPAN BLUE', or 'OTHER' if the exclusion dye you used does not appear on the list. If 'OTHER' is selected, type the name of the exclusion dye in the textbox below. If the type of exclusion dye is not known, select 'UNKNOWN'. Islet viability was not determined at this stage, select 'NOT DONE'.
70.1.11.3	Islet Viability	Indicate the islet viability of the islets assessed in the final islet preparation. Islet viability should be expressed as a percentage. Percentage is expressed as a % not as hundredths. For example, if the islet viability was 33%, enter '33' not 0.333.
71	Final Islet Prep total volume	Indicate the total volume of the final islet preparation. The total volume should include the entire islet preparation. Total volume should be expressed in units of mL.
72	Gram stain	Indicate if the gram stain has 'NO ORGANISM SEEN' or 'POSITIVE'. If the gram stain is positive, select if it is 'GRAM POSITIVE' or 'GRAM NEGATIVE' in the drop down box below. If the gram stain is not known, select 'UNKNOWN'. If the gram stain was not performed, select 'NOT DONE'.
72.1	Gram stain positive	If the gram stain is positive, indicate if it is 'GRAM POSITIVE' or 'GRAM NEGATIVE'. If the result is not known, select 'UNKNOWN'.
73	Aerobic culture	Indicate if the aerobic culture has 'NO GROWTH' or 'POSITIVE'. If the aerobic culture is positive, indicate the organisms found in the textbox below. If the aerobic culture is not known, select 'UNKNOWN'. If the aerobic culture was not performed, select 'NOT DONE'.
74	Anaerobic culture	Indicate if the anaerobic culture has 'NO GROWTH' or 'POSITIVE'. If the anaerobic culture is positive, indicate the organisms found in the textbox below. If the anaerobic culture is not known, select 'UNKNOWN'. If the anaerobic culture was not performed, select 'NOT DONE'.
75	Fungal culture	Indicate if the fungal culture has 'NO GROWTH' or 'POSITIVE'. If the fungal culture is positive, indicate the organisms found in the textbox below. If the fungal culture is not known, select 'UNKNOWN'. If the fungal culture was not performed, select 'NOT DONE'.
76	Mycoplasma	Indicate if the mycoplasma has 'NO ORGANISM SEEN' or 'POSITIVE'. If the mycoplasma is positive, indicate the organisms found in the textbox below. If the mycoplasma is not known, select 'UNKNOWN'. If the mycoplasma was not performed, select 'NOT DONE'.
77	Total endotoxin units in final preparation	Indicate the total endotoxin units in the final preparation. If endotoxin units are recorded as a specific value, then enter that number in the first textbox next to the 'EU/mL' unit label. If your lab does not report a specific value, for example it reports <0.5, then enter '<0.5' in the '<EU/mL' unit label. If the endotoxin units are not known, select the 'UNKNOWN' checkbox to the right. If the endotoxin units were not obtained, select the 'NOT DONE' checkbox to the right.
78	Mouse bioassay conducted	Indicate whether or not a mouse bioassay was conducted. If a bioassay was conducted, select 'YES' and answer the questions below. If a bioassay was not conducted, select 'NO' and click on the [Submit] button at the bottom right of the page.
78.1.1	Mouse ID	Indicate the lab ID number used by your center to identify the mouse experiments. If your lab does not use mouse experiment ID numbers to identify mouse experiments, you may enter N/A or DOES NOT APPLY in the textbox to the right.
78.1.2	Mouse model	Select the type of mouse model used. If 'OTHER' is selected, specify the model in the textbox below. If the type of mouse model used is not known, select 'Unknown'. If a mouse model was not used, select 'Not Done'.
78.1.3	Mice transplanted	Indicate the total number of mice transplanted using islets from the isolation.
78.1.4	IEQs transplanted	Indicate the total number of IEQs transplanted per mouse. Units are expressed in IEQ/kg bodyweight
78.1.5	Organs	Select the organ into which the islets transplanted. If the organ used does not appear on the list, select 'OTHER' and enter the organ in the textbox below.

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78.1.6	Route of transplantation	Select the route of transplantation. If the route of transplantation does not appear on the list, select 'OTHER' and enter the route of transplantation in the textbox below.
78.1.7	Percentage of mice cured	Indicate the percentage of mice cured. This number should be the percentage of total mice cured.
78.1.8	Judging a cure	Indicate the outcome variables used to determine whether or not the mice were cured. Check all that apply. If the criteria your laboratory uses does not appear on the list, select 'OTHER' and enter the outcome variable(s) your laboratory used in the textbox below.